

REMARKS

The present application relates to inbred maize plant and seed PH94T. Claims 1-12 are pending in the present application. Claim 2 was previously amended in the Amendment filed April 18, 2005. Applicant acknowledges the addition of claims 13 through 36. No new matter has been added by way of amendment. Applicant respectfully requests consideration of the claims in view of the following remarks.

Detailed Action

A. New Matter

The specification is objected to by the Examiner for introducing new matter. Applicant has canceled the last sentence of the first paragraph on page 76, thereby alleviating this objection.

B. Claims

Applicant acknowledges the addition of claims 13 through 36. The new claims do not add new matter as there is support for the claims in the originally filed specification. Support for the specific items can be found within the specification for herbicide tolerance on pages 44-46; insect resistance and resistance to bacterial, fungal, nematode or viral disease on pages 40-44; yield enhancement on pages 35-36; waxy starch and improved nutritional quality on pages 35-36; male sterility on pages 2-4 and 47-48; restoration of male fertility on pages 2-4 and 0-5 generations on pages 4-8. No new matter has been added. Applicant respectfully requests consideration of the claims in view of the following remarks.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 11 and 12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states "claims 11 and 12 are omnibus claims because it refers to a Table". (Office Action, p. 3).

Applicant respectfully traverses this rejection. According to MPEP §2173.05(s) incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no *practical* way to define the invention in words and where it is *more concise* to incorporate by reference than duplicating a drawing or table in the claim"

(emphasis added). Applicant asserts that there is no practical or concise way to include Table 4 into claims 11 and 12. Further, the reference to the "SSR loci listed in Table 4" enhances the level of specificity in the claim, which is consistent with *Ex parte Fressola*, 27 USPQ2d, 1608, 1609 (B.P.A.I. 1994). Applicant therefore respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-12 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states the rejection is repeated for the reasons of record set forth in the Office Action of November 19, 2004.

Applicant traverses this rejection. Applicant reiterates that the written description requirement has been satisfied by the actual reduction to practice of F1 hybrid seed/plant produced by inbred maize line PH94T, by the deposit of a common identifying structural feature of the claimed F1 hybrid seed and plants, by the morphological description of Table 1 and by the description of the SSR marker profile in Table 4 of the specification. (See specification, p. 27-30 and p. 70-73, respectively).

The Examiner states that as in *Enzo*, "here the deposited inbred seed does not correspond exactly to the claimed F1 hybrid". Further the Examiner cites, "[h]owever, the functions of the claimed hybrid plants have not been correlated to the set of chromosomes originating from the deposited PH94T seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited PH94T seed". (Office Action, p. 4-5).

In order to satisfy the written description requirement, the Applicant "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). In essence, "the description must clearly allow persons of ordinary skill in the art to recognize that [the Applicant] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989). An Applicant's claims are described where they set forth and define "structural features commonly possessed by members of the genus that distinguish them from others." *Regents of University of California*,

119 F.3d at 1568, 43 U.S.P.Q.2d at 1406 (emphasis added). For inventions similar to the present Applicants, "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). The Board of Patent Appeals & Interferences has also confirmed the sufficiency of a deposit for seed and plants in the case of *Ex Parte C*, 1992 WL 515817 p. * 5, 27 U.S.P.Q.2d 1492, 1496 (B.P.A.I. 1992), where it stated that "[t]he claimed soybean is described in the specification to the extent that there is no question that appellant was in possession of the invention as of the time the instant application was filed. Because seed is to be deposited in a public depository, the specification is enabling and sets forth the best mode of carrying out the invention."

Further, in order to satisfy the written description requirement, Applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art". *Regents of University of California v. Eli Lilly*, 119 F.3d 1559, 1569, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) (citing as analogous argument *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q.2d 214, 218 (Cust. & Pat. App. 1976)). Consistent with this principal, the Board of Patent Appeals & Interferences, in a case involving the written description requirement as applied to seed and plants, stated "[i]f in making the latter comment the examiner is requiring appellants to have reduced to practice each possible plant within the scope of the claims, such a position is legally incorrect. The specification need only teach one skilled in the art how to make and use the claimed invention. How the specification does so, whether by way of the written word or actual examples, is of no moment." *Ex parte Gerardu C.M. Bentvelsen et al.*, 2001 WL 1197757, p. *2 (B.P.A.I. 2001). In addition, a claim to the genus of F1 hybrids made with a patented inbred was expressly acknowledged by the U.S. Supreme Court when it stated that "...a utility patent on an inbred plant line protects the line *as well as all hybrids* produced by crossing that inbred with another plant line." *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143; 122 S.Ct. 593, 604; 60 U.S.P.Q.2d 1865, 1873 (2001) (emphasis added). Therefore, Applicant submits that based on the data provided in the specification and the above the function of the hybrid has been correlated to the set of chromosomes originating from the deposited PH94T seed.

In addition to description by structure, the written description requirement may be satisfied by disclosing functional characteristics where there is a correlation between structure and function. The Federal Circuit has stated that the written description requirement may be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics." *Enzo Biochem, Inc.*, 323 F.3d at 964, 63 U.S.P.Q.2d at 1613 (quoting and adopting the USPTO's Written Description Guidelines, 66 Fed. Reg. 1106, No. 4 (2001)). As stated *supra*, Applicant has disclosed sufficiently detailed, relevant identifying characteristics in the Tables provided and therefore has in fact complied with the requirement of written description.

The Examiner further states "the specification does not describe the traits that are associated with the SSR loci of Table 4". The Examiner goes on to state that "[w]ithout a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant". (Office Action, p. 5).

Applicant reiterates that the SSR profile has been described in the present application and the Examiner's assertion regarding the sequences of the SSR markers not being confirmed is improper. (Specification, p. 68-75). This unique set of chromosomes can be described by the molecular markers disclosed and can be further be characterized by molecular marker methods known to those of skill in the art. (Specification, p. 7 and 68-75). Applicant points out that the intention of the production of hybrids is to retain the homozygosity of the inbred maize lines, and the inbred genotype will be preserved in the hybrid. As stated in the specification: "[i]nbred maize lines are typically developed for use in the production of hybrid maize lines. Inbred maize lines need to be highly homogeneous, substantially homozygous and reproducible to be useful as parents of commercial hybrids. There are many analytical methods available to determine the homozygotic stability and the identity of these inbred lines" as discussed *supra*. (Specification, page 24, lines 22-26). Therefore, the Examiner's assertions are respectfully incorrect because in the present invention the genomic structure of PH94T is shared by the claimed genus of hybrids, due to the highly homogenous nature of the PH94T genetic complement. These are known facts to one of ordinary skill in the art of inbred maize lines and are sufficient to provide the distinguishing characteristics necessary to comply with 35 U.S.C. § 112, first paragraph. The

Applicant has thus provided "distinguishing characteristics" of the claimed genus. As explained above, these specific identifying characteristics are the cells and/or chromosomes of PH94T described in the deposit of the present application and present in the claimed F1 hybrid genus. The cells and/or chromosomes are present in the genus of F1 hybrids made with PH94T and absent in the genus of F1 hybrids not made with PH94T. To require Applicant to further describe aspects of the claimed invention that are not the point of patentability of the genus extends the written description requirement beyond the legal standard. Applicant would also like to note that the Examiner does not specify how the rejection under 35 U.S.C. § 112, first paragraph, requiring traits to be associated with SSR markers profile is discussed or required under the USPTO's Written Description Guidelines or MPEP. Thus Applicant respectfully submits the claimed invention is in accordance with the written description guidelines.

The Examiner further states that *Eli Lilly* stands for the proposition whereby "the members of genus shared a common function". The Examiner goes on to state that in the "instant application, the specification does not describe the functions (i.e. morphological and physiological traits) of the claimed hybrids, and does not correlate the functions of the hybrids with the structure of the genetic complement or the set of chromosomes from PH94T". (Office Action, p. 6).

Applicant submits that in accordance with the *Eli Lilly* standard recited by the Examiner, the genus of F1 hybrids encompassed by Applicant's claims 1-10 are described with precise definition in a manner which provides structure sufficient to distinguish an F1 hybrid made with PH94T from an F1 hybrid not made with PH94T. This is because cells and/or chromosomes of inbred line PH94T provide an identifying structural feature possessed by all members of the claimed genus. (Specification, p. 70-73). In addition, new claims 13-36 were added to further characterize the claimed invention. Therefore, since Applicant has deposited the seed of inbred maize PH94T and provided the marker profile in Table 4, thereby allowing one skilled in the art to identify the F1 hybrids in relation to the structural feature of the claimed invention, the written description requirement of 35 U.S.C. § 112, first paragraph has been met.

Further, the primary utility of an inbred is in the hybrid it will produce, and Applicants have provided ample description of the hybrids produced by PH94T in the application as filed. (Specification, p. 1, ll. 20-25; pp. 27-30, Table 1; pp. 62-67, Table 3A-3C). As stated in the MPEP, §2163(II)(A)(3)(a)(ii), the written description requirement for a genus may be satisfied

by sufficiently describing a representative number of species actually reduced to practice. These hybrids are thus representative of the hybrids produced using PH94T as a parent. This is sufficient to meet the written description requirement. *See Ex parte Garing*, p. 18 (B.P.A.I. 2005) (stating "[i]n addition, the examiner appears to recognize . . . that appellant's specification describes an exemplary hybrid wherein one parent was a plant of the corn variety [inbred number]. . . Accordingly, it is unclear to this merits panel what additional description is necessary.") The Applicant has thus satisfied the written description requirement for claims 1-10 and new claims 13-36.

The Examiner goes on to state that "[o]ne cannot predict which set of alleles a hybrid will receive from its parent". Further the Examiner states "Applicant has provided no evidence that these F1 hybrids are reproducible". (Office Action, p. 7).

Applicant respectfully traverses. Applicant asserts that it is well known to one of ordinary skill in the art that the F1 hybrids claimed are reproducible. As stated *supra*, that use of inbred maize lines is for them to be "highly homogeneous, substantially homozygous and reproducible to be useful as parents of commercial hybrids". (Specification, p. 24, ll. 23-25). As asserted previously, Applicant has identified a structural feature which is present in each of the members of the genus claimed in claims 1-10 and new claims 13-36. The written description requirement for these claims has therefore been satisfied. *See Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406.

The Examiner concludes by stating that "hybrids that do not share both of the same parents will not have the same traits and the fact that they share one set of chromosomes from PH94T does not provide any information concerning the morphological and physiological characteristics that will be expressed by the hybrids". (Office Action, p. 10).

The legal standards for the written description requirement are discussed *supra*, and the written description requirement does not mandate a description via morphological and physiological characteristics.

Applicant refers the Examiner to the case of *Ex Parte Tanksley*, 37 USPQ2d. 1382. In that case, the Examiner desired that Tanksley claim according to sequence data to "better characterize the cDNA clones" and "facilitate a complete search of the prior art" and issued a § 112 first paragraph written description rejection. The Board held that "the section 112 rejection amounts to a requirement...that the appellants amend their claims in a specified manner...We

find no language in the statute or case law which would support that requirement." The Board, in treating the section 112 first paragraph rejection as a § 112 second paragraph rejection, held that "[i]n our judgement, a patent applicant is entitled to a reasonable degree of latitude in complying with the second paragraph of 35 U.S.C. § 112 and the examiner may not dictate the literal terms of the claims for the stated purpose of facilitating a search of the prior art. Stated another way, a patent applicant must comply with 35 U.S.C. § 112, second paragraph, but just how the applicant does so, within reason, is within applicant's discretion." *Id.* at 1386.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Summary

Applicant acknowledges that claims 1-12 are deemed free of the prior art. The Examiner states the prior art fails to teach or fairly suggest a hybrid maize seed/plant produced from the inbred maize PH94T, wherein the hybrid comprises at least one set of chromosomes of inbred PH94T. This clearly indicates that maize inbred line PH94T as a whole is considered to be distinguishable from the prior art for the purposes of novelty and non-obviousness. Applicant thanks the Examiner for recognizing that prior art hybrids do not comprise one set of chromosomes of inbred PH94T.

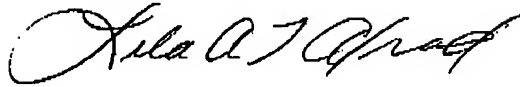
Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

This Amendment accompanies a Request for Continued Examination (RCE). Please charge Deposit Account No. 26-0084 the amount of \$790.00 per the attached RCE Transmittal. Please also charge Deposit Account No. 26-0084 the amount of \$1,200 for 16 additional claims over 20 (\$50 each) and 2 additional independent claims over 3 (\$200 each). No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



Lila A. T. Akrad, Reg. No. 52,550
McKEE, VOORHEES & SEASE, P.L.C.
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No: (515) 288-3667
Fax No: (515) 288-1338
CUSTOMER NO: 27142

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Attorneys of Record